Notice of Allowability	Application No.	Applicant(s)	
	09/750,022	ISAACS, INDU J.	
	Examiner	Art Unit	
	Chih-Min Kam	1653	
The MAILING DATE of this communication appears on the cover sheet with the correspondence address All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS. This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.			
1. This communication is responsive to 1/04/05.			
2. The allowed claim(s) is/are <u>1-51,53-55 and 58-78.</u>			
3. The drawings filed on 29 December 2000 are accepted by the Examiner.			
<ul> <li>4.  Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). <ul> <li>a)</li></ul></li></ul>			
Attachment(s)  1. ☑ Notice of References Cited (PTO-892)  2. ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)  3. ☐ Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No./Mail Date			

U.S. Patent and Trademark Office PTOL-37 (Rev. 1-04) Application/Control Number: 09/750,022

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An Examiner's Amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Michele Simkin on March 23, 2005.

## Examiner's Amendments to the Claims:

Cancel claim 52.

Claim 59 has been amended as follows:

(Currently amended) The GLP-2 formulation of claim 21, wherein the GLP-2 receptor antagonist has either (1) an amino acid substitution selected from the group consisting of Asp<sup>15</sup>, Phe<sup>22</sup>, Thr<sup>29</sup>, Thr<sup>32</sup>, Asp<sup>33</sup>, and combinations thereof; or (2) an amino acid substitution of Ala at position 2 by an amino acid selected from the group consisting of Leu, Cys, Glu, Arg, Trp and PO<sub>3</sub>-Tyr, wherein the residue or position for the amino acid substitution is numbered according to a mammalian GLP-2.

The following is an Examiner's Statement of Reasons for Allowance: The following references appear to be the closest art to the claimed invention. Knudsen *et al.* (WO 99/43361) teach a pharmaceutical composition comprising a GLP-2 derivative or analog, an isotonic agent such as mannitol, a buffer of histidine or sodium phosphate, a pharmaceutical acceptable carrier, a preservative and a surfactant; Kornfelt *et al.* (U. S. Patent 5,652,216) disclose using stabilizing amount of a pharmaceutically acceptable ampholyte such as glycine, histidine or GlyGly in a pharmaceutical preparation comprising glucagons. However, Knudsen *et al.* either alone or in combination with Kornfelt *et al.* do not teach or suggest a GLP-2 formulation comprising a medically useful amount of GLP2 or an analog thereof, a phosphate buffer, L-histidine for stabilizing the formulation and a bulking agent of mannitol and sucrose. Buhl *et al.* (J. Biol. Chem. 263, 8621-8624 (1988)) teach amino acid sequences of GLP-2 from different species; and Lund *et al.* (J. Biol. Chem. 258, 3280-3284 (1983)) teach nucleotide and corresponding deduced amino acid sequences of cDNA encoding two anglerfish pre-proglucagons, where the GLP-2 sequence in the angler fish pre-proglucagon is different from the mammalian GLP-2. Therefore, the claims are allowable over the art of record.

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Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (571) 272-0948. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached at 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Chih-Min Kam, Ph. D.

Patent Examiner

**CMK** 

March 23, 2005

**JON WEBER** 

SUPERVISORY PATENT EXAMINER